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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,985	09/15/2005	Karl Lintner	SEDERM3.3-011	4999

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LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER	
AULAKH, CHARANJIT	
ART UNIT	**PAPER NUMBER**
1625	

MAIL DATE	DELIVERY MODE
07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,985	LINTNER, KARL	
	Examiner	Art Unit	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,38,42-45 and 56-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *37,38 and 42-45* is/are allowed.

6)☒ Claim(s) *56-68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. According to paper filed on July 2, 2007, the applicants have filed a RCE; canceled claim 46, amended claims 37, 38 and 43 and furthermore, have added new claims 56-68.

2. Claims 37, 38, 42-45 and 56-68 are now pending in the application.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 56-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The following eight different factors (see Ex parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on atleast four of the above mentioned eight different factors such as quantity of experimentation

necessary, the amount of direction or guidance provided, presence of working examples, the state of the prior art, unpredictability and the breadth of claims.

The specification teaches inhibitory effect of a single compound (2, 9-diacetyloxy-1,10-dimethoxy-6-methyl-noraporphine) on G-3-PDH activity, peroxidation and melanogenesis in vitro (see examples 5-7 on pages 22-25). However, there is no teaching or guidance present in the specification that this inhibitory effect of a single compound on G-3-PDH activity, peroxidation and melanogenesis is enhanced, attenuated or even maintained in the presence of any single active substance. There is lot of unpredictability of the outcome of combination treatment due to drug interaction. There is no teaching or guidance present in the specification that how the instant compounds in combination with additional hundreds of thousands of compounds will decrease pigmentation, slim, reduce cellulite or firm the skin of a person. There is no teaching in the specification or prior art for well known utility of structurally closely related compounds alone or in combination with any other active substance in these conditions. The instant compounds in combination with active substances encompass several hundreds of thousands of compounds and therefore, in absence of such teachings, guidance, unpredictability and presence of working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds in combination with additional hundreds of thousands of active substances in known animal models of dermatological conditions mentioned in instant claims 37 and 38 and hence their utility for treating such conditions

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 64-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Krell (WO 99/16441).

Krell discloses Aporphinoid compounds, pharmaceutical compositions containing these compounds for treating MMP-mediated diseases. The compound, glaucine (see compound 12 on page 10) as well compounds 30-40 (see examples 30-40 in columns 13-14) disclosed by Krell anticipate the instant claims when the instant compound is represented by 1,2, 9, 10-tetramethoxy-6-methyl-noraporphine.

6. Claims 64-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Cortes (J. of natural products).

Cortes discloses noraporphine compounds. The compounds 6 and 8 (see page 865) disclosed by Cortes anticipate the instant claims when the instant compound is represented by 2, 9-diacetyloxy-1,10-dimethoxy-6-methyl-noraporphine.

7. Claims 64-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen (Planta Medica).

Chen discloses Antiplatelet and vasorelaxing actions of some aporphinoids. The compound 12 (see table on page 134) disclosed by Chen anticipate the instant claims when the instant compound is represented by 1, 2, 10-trimethoxy-9-hydroxy-6-methyl-noraporphine.

8. Claims 37, 38 and 42-45 are allowed..

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

C. S. Aulakh

Charanjit S. Aulakh
Primary Examiner
Art Unit 1625